EXHIBIT N

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March 29, 1983

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Subject: HUMAN RETRIEVAL SPECIMENS FROM DR. ROGER GREGORY, NORFOLK SURGICAL GROUP

ERF ACCESSION NO.

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PROJECT NO. 47201

SUMMARY

Formalin fixed tissue samples containing Dacron graft material and PROLENE* (polypropylene) sutures were submitted for evaluation from the Norfolk surgical group. Sample #1 was resected from a false aneurysm from a patient six years after an aorto-bifemoral graft was inserted using 6-0 PROLENE suture. Sample 2 was resected 5.5 years after an aorto-femoral bypass graft was inserted using 5-0 PROLENE suture.

Segments of 5-0 PROLENE from specimen #2 were carefully removed from the graft and tested for breaking strength evaluation (BSE). Results were 54% breaking strength remaining when measured against a similar size control. No segments of an adequate length were recovered from sample #1 to be tested for breaking strength. PROLENE sutures from both samples displayed surface cracking when examined by light microscopy.

Histological examination revealed a cellular response consistent with other long-term implants of Dacron graft. The reaction surrounding the PROLENE suture was minimal in all cases.

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SAMPLE #1

Description

A fixed tissue specimen measuring approximately 1.5cm x 0.8cm was received for examination. Grossly, tissue was adherent to only one side of the specimen, Figure 1. On the fabric side of the specimen, a knot and running suture line was visible, Figure 2. This specimen was resected from a false aneurysm 6 years after an aorto-bifemoral graft was inserted using 6-0 PROLENE sutures. (See attached memo Gregory to Marshall, patient Miriam Brown, 2/4/83).

Suture Evaluation

Three suture segments were carefully removed from the tissue specimen. These measured approximately .08cm, 1.2cm and 3cm (with knot), respectively. These specimens were considered too short for breaking strength evaluation. The diameters of the sutures were between .080mm to .070mm which is consistent with USP standards for a nonabsorbable 6-0 suture. Light microscopic evaluation of these strands revealed surface cracking, Figure 3.

Histological Evaluation

The histological observations of the sections revealed the presence of Dacron graft fibers infiltrated by macrophages, giant cells and fibroblasts. An acellular eosinophilic material was also seen surrounding the graft fibers. Adjacent to the graft segment was a thick capsule of well-vascularized connective tissue. Cracking of the suture surface was also evident in a longitudinal section of PROLENE located near the graft fibers, Figure 4. The cracking appeared along only one edge of the PROLENE and was especially prominent when viewed with polarized light, Figure 5.

SAMPLE #2

Description

A fixed tissue specimen measuring 3cm x 3cm was received for examination. Grossly, a segment of Dacron measuring 1.3cm was firmly adherent to the tissue mass and a PROLENE suture line was evident, Figure 6. This specimen was resected 5.5 years after an aorto-femoral bypass graft was inserted using 5-0 PROLENE suture. (See attached memo Gregory to Marshall, patient Paul Newman, 2/4/83). Another segment of PROLENE was free-floating in the fixative container and presumably was removed from this graft.

Suture Evaluation

One length of suture, with a knot, was carefully removed from the tissue specimen. The legs measured 1cm and 2.5cm, respectively. The free length of suture measured 8.2cm and had areas of kinks and instrument damage on the surface, Figure 7. The diameter of the strands were .145mm which is consistent with USP standards for a 5-0 nonabsorbable suture. A 4cm segment from the long strand, which was relatively free from instrument damage, was used for breaking strength evaluation. Measured against a 5-0 PROLENE

control, this segment had 54% strength remaining. Light microscopic evaluation of this strand revealed surface cracking identical to Sample #1, Figure 8.

Histological Evaluation

The histological observations of this tissue revealed a row of Dacron graft fibers infiltrated with foreign body giant cells, macrophages and fibroblasts. An acellular eosinophilic fibrinoid material was located among the graft fibers in some areas. This fibrinoid material was in varying states of degredative change with focal areas of basophilia suggestive of early mineral deposition. Located adjacent to the graft were segments of dense fibrous connective tissue measuring approximately 1mm x 3mm. These areas may correspond to normal vascular tissue adjacent to the graft site. Remnants of internal elastic membrane were visible, based on an elastic tissue stained section, and the normal intima had evolved into a dense layer of collagen fibers. No endothelial cells were present on what was judged to be the luminal surface. Only one cross sectional profile of PROLENE was contained in this slide. No evidence of cracking was noted. The cellular response to the suture material was minimal.

CONCLUSION

The histological picture of the grafts in this study are consistent with other long-term human retrieval graft specimens we have evaluated in the past. This includes a foreign body response to the graft fibers along with a degraded acellular infiltrate. The tissue response to the PROLENE sutures was minimal in all cases.

Surface cracking was noted on the PROLENE sample from both explants. Why the cracking occurred or if this condition contributed to the loss of breaking strength (54%) could not be determined from this type of examination. It could also not be determined when or how the instrument damage occurred on the strand from Sample #2.